Remarks/Arguments

Claims 16-26 are pending. Claims 18-26 are new. Claims 16-17 are amended. Support for the amendments to claims 16-17 is found in the specification at, for example, paragraph 0032. Support for the new claims is generally found throughout the specification. No new matter is present.

1. Claim Objections

Claims 16 and 17 were objected to for the use of the acronym "IRS2" without first defining what it represents. As amended, Claims 16 and 17 now recite "insulin receptor substrate 2 (IRS2)."

2. Rejection under 35 U.S.C. § 112, second paragraph

Claims 16 and 17 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because the claims lack a step that clearly relates back to the preamble. Applicants believe the rejection is made moot by the instant amendments to the claims.

3. Rejection under 35 U.S.C. § 102

Claim 17 was rejected under 35 U.S.C. § 102(b) as anticipated by U.S. Patent No. 5,858,701. Claim 17 relates to increased expression of IRS2 under conditions that promote IRS2 signaling. As amended, the claim requires that the test compound identified as a modulator of expression from an IRS2 promoter modulates the activity of IRS2 or an IRS2-containing complex but not bind to any non-IRS2 protein in the absence of IRS2. The Applicant respectfully asserts that the claimed subject matter is not disclosed by the'701 patent and requests that the rejection be withdrawn.

4. Rejection under 35 U.S.C. § 103

Claim 16 was rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 5,858,701 ("the '701 patent") in view of U.S. Patent No. 5,688,655 ("the '655 patent"). According to the Examiner, the '701 patent teaches a screening method using a population of cells in which IRS2 is misexpressed, and the use of such cells to test a given substance for its effect on some aspect of IRS2 metabolism. The '701 patent also teaches a method for evaluating the ability to modulate IRS2 binding to an IRS2 binding ligand. However, it is conceded that the '701 patent does not explicitly teach comparison of results from a test cell population that overexpresses IRS2 to a control cell population that produces IRS2 at a lower level or not at all.

On the other hand, it is asserted by the Examiner that the '655 patent teaches that comparison, namely, a method for determining whether a substance is an inhibitor or an activator of a protein which employs a test cell which overproduces a selected protein relative to a control cell that produces the protein at a lower level or not at all. According to the Examiner, one of ordinary skill in the art would have been motivated by the "rapid, yet powerful screening system" of the '655 patent, and could have reasonably expected success.

As amended, Claim 16 recites "examining the test cell for modulation of an IRS2-mediated cellular signal." Accordingly, the rejection of Claim 16 is believed moot. In particular, the method taught by the '655 patent for identifying an activator or inhibitor of a protein requires one of ordinary skill in the art to identify a "graded cellular response" dependent on production of a protein of interest (*see, e.g.*, Col. 2, ll. 39-47), or more generally a "responsive change in a phenotypic characteristic" that results when the protein is overproduced in the test cell (as claimed). For example, the '655 patent discloses test cells in which PKC-β1 is overproduced, which cells exhibit a graded cellular response in, *e.g.*, growth rate, and morphology. The capacity of a test compound to bind to and activate or inhibit PKC-β1 activity is determined by its ability to modulate the responsive phenotypic characteristic.

One of ordinary skill in the art would not be motivated to combine the teachings of the '701 patent and the '655 patent. This is because the '701 patent does not disclose the responsive change in a phenotypic characteristic of a cell that overproduces IRS2 as taught in the '655 patent. As a result, the skilled practitioner would not understand how to use the method disclosed in the '655 patent to identify a compound that modulates IRS2 function. In fact, aside from the increased level of IRS2 in the test cell, IRS2 overproduction per se will not invoke a responsive change in a phenotypic characteristic that is disclosed in the '655 patent.

In contrast, the instant application discloses particular features of a cell that overproduces IRS2, such that one of ordinary skill in the art can identify modulators of IRS2 function. In particular, the instant application discloses that the test cell should be examined for modulation of an IRS2-mediated cellular signaling function. Modulation of such signal transduction elements can be observed, for example, by cell culture under conditions that stimulate insulin secretion and observation of the effects of a test compound on a component of the IRS2 signaling cascade.

For the same reasons, a skilled practitioner applying the cell based assay method of the '655 patent would have no expectation of success. Whereas the '655 patent discloses a

method based on identification of a responsive change in a phenotypic characteristic evoked in a test cell that overproduces a particular protein of interest, no such responsive phenotypic characteristic resulting from overexpression of IRS2 is disclosed or suggested.

Accordingly, the Applicant believes that the subject matter of Claim 16 is not obvious and respectfully requests that the rejection be withdrawn.

Conclusion

In view of the above amendments and remarks, applicants believe that the claims are in condition for allowance. The Examiner is invited to contact Applicants' undersigned attorney if there are any questions or issues that the Examiner feels can be resolved in a telephone interview.

Respectfully submitted,
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